IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David M. DEBOER, et al.

Application No.: 10/034,926

Filing Date: October 29, 2001

For: INJECTION-ASSISTING PROBE FOR MEDICAL INJECTOR ASSEMBLY

Confirmation No.: 2483

Group Art Unit: 3763

Examiner: LoAn H. Thanh

Attorney Docket No.: 88066-5199

DECLARATION UNDER 37 C.F.R. § 1.132
OF JULIUS SUND

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. I, Julius Sund, hereby declare that I am a citizen of the United States of America and reside in Hennepin County at 910 Windemere Curve in Plymouth, Minnesota. In 1982, I received a Bachelor of Science degree in Business Administration, and in 1985 a Bachelor of Science in Mechanical Engineering, both from the University of Minnesota. I am an employee of Antares Pharma, Inc., a Delaware corporation, in the position of Executive Director of Manufacturing-Devices Group, with responsibility for the manufacture of needle-free injection devices and the nozzles used by these devices. My responsibilities include manufacturing, manufacturing improvements, and support for the development of future needle-free injection devices. I have 19-plus years of experience working as an engineer, including over 14 years in the medical device field, and 10 years working with the manufacture and operational design of jet injectors. I have been an employee of Antares Pharma and its predecessor company for 10 years. During this time, I have been responsible for the design and qualification of tooling for the production of plastic nozzle assemblies for injection devices. A key part in the qualification and production of the nozzle assemblies is design and manufacture of the core pins that define both orifice and the discharge channel.

2. I have reviewed and understand the above-identified patent application, the pending claims with the present amendments, the Office Actions mailed on August 25, 2005, the reference cited therein (U.S. Patent No. 5,599,302 to Lilley et al. (the "Lilley patent")), and the Amendment submitted herewith. I am making the following statements as one of ordinary skill in the art in support of the patentability of the claims in this application.

3. Purporting to use the broadest interpretation of the claims as they stood prior to the present amendment, the Office Action made it clear that the ratios defined in the claims were being measured taking the entire length of the nozzle assembly 20A or 20B shown in Figs. 10 and 11 of the Lilley patent, which the Office action refers to as a "probe," but taking only the diameter at the tip of the orifice 24. The Office Action further asserts that that orifice 24 is "very small," and thus "it is considered to be clearly shown that the length of the channel to the diameter of the orifice is greater than 6/1." The Examiner has contended that Lilley teaches an injection assisting probe with a discharge channel that has an orifice diameter of about 0.07-0.4 mm. The argument is made that looking at Figs. 1-6, and specifically at Figs. 10 and 11, leads to the conclusion that the length of the discharge channel is at least 0.024 inches and that the length to orifice ratio is inherently greater than 6/1 or 9/1. The Office action further argues that it would be considered to be inherent that "length to orifice ratio" is greater than 6/1 or 9/1.

4. In my opinion, however, and as explained below, this is an interpretation that cannot be given to the claims, and it is not the "orifice" diameter that is being compared to the length, but the diameter of the portion of the discharge channel that terminates in the orifice.

5. Specifically, claim 1 defines an injection device with a discharge channel that includes a channel portion that terminates in an orifice. The channel portion and has a length to average diameter ratio of greater than 6/1. Claim 16 defines that the channel portion that ends at an orifice that has the same diameter as the channel portion over the length of the channel portion, and claim 20 also defines that the channel portion ends at an orifice and that the ratio is of the length to the average diameter of the channel portion. Each of these claims also defines a fluid chamber with which the other end of the channel is in fluid communication. Also, claim 21 further defines that the channel diameter is substantially equal to the orifice diameter adjacent thereto, which is where the ratio is measured, and claim 22 further defines that the channel has a constant diameter where the ratio is measured.

6. Based on the disclosure in the application, one of ordinary skill in the art would have understood that the ratio that provides the surprising benefits described in the last paragraph on page 8 and the first paragraph on page 9 is the ratio of length to diameter of the downstream portion of the channel that ends at the opening, not necessarily of the entire

interior of the probe or of the entire portion ahead of the plunger.[1] Also, the description of Fig. 11 of the application explains that, "The interior of the probe [has] a section 57 to accommodate the plunger and a tapered section 58 to funnel the medicament to the *discharge channel 56* and out the discharge orifice 59 during operation."[2] It is thus clear that the discharge channel includes that most downstream portion of the interior of the probe, which terminates in the orifice 59 in this embodiment. It is also clear from the description that the length-to-diameter ratio is the ratio of the length of a section of the discharge channel divided by the average diameter over the length of channel that is measured. Claims 1 and 20 clearly define that the diameter measured is the average diameter over the length of the channel over which the ratio is obtained.

7. The Lilley patent also has a short discharge channel ahead of a circular cone 28,28', which is ahead of ampule chamber 26. In addition, there is even a portion of the nozzle assembly 20,20' that houses the plunger 30A,30B. In my opinion, it is improper to measure the ratio over a length that includes the entire Lilley nozzle assembly, which is done in the Office Action, or even of the portion ahead of the plunger 30A,30B. This is because the length of the entire Lilley nozzle assembly includes the length of the ampule, which is a fluid chamber, and even includes a portion behind the fluid chamber. To the contrary, the discharge channel in each of claims 1, 16, and 20 is in fluid communication with the fluid chamber.

8. Furthermore, claim 27 recites that a the fluid chamber is significantly larger in cross-sectional area than the channel portion, claim 28 recites that the nozzle assembly has a tapered portion between the fluid chamber and the discharge channel, and claim 29 recites that the tapered portion is configured to accommodate the plunger. These features are present behind the portion of the channel over which the ratio is measured, and in my opinion, one of ordinary skill in the art would further interpret these claims as requiring a much shorter length measurement for the claimed ratio than used by the Examiner.

9. Also, especially with the present language of the claims, even when measured as proposed in the Office Action, it is improper to merely measure the diameter at the tip of the Lilley orifice and consider this an average diameter in a length to average diameter ratio. In the Lilley patent, there is no length that can be measured over which the average diameter is sufficiently small so that the length to average diameter ratio will be at least 6/1, as recited

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[1] Drawings accompanying the Office Action show a line dividing the portion of the nozzle assemblies 20A,20B ahead of the plungers 30A,30B in Figs. 10 and 11 of the Lilley patent.
[2] Application, page 7, lines 9-11 (emphasis added).

in claims 1 and 20. Similarly, there is no potion of a discharge channel in the Lilley patent that has the same diameter as the orifice and has at least a length to diameter ratio of 6/1, as recited in claims 16, 21, or 22.

10. Consequently, is my opinion the interpretation of the claims in the Office Action is very different than would be understood by one of ordinary skill in the art, and there is no disclosure or inherency of a channel portion with a ratio of at least 6/1 as defined in any of the claims. For this same reason, a ratio of 9/1, as defined in claims 3, 18, 19, and 23 is also not shown or inherent in the Lilley patent description.

11. Furthermore, in the manufacture of jet injection nozzles, it is traditionally been desired to keep the length of the discharge channel as small as possible, and certainly to provide a length to average diameter ratio of less than 6/1. This is because the channel is traditionally made using a core pin to form the orifice and portion of the discharge channel leading thereto. The core pin is typically a fragile and precise molding element, and it becomes increasingly more fragile as its length to diameter ratio is increased, which hinders the manufacturing of the device, decreasing the reliability, durability, and expense of the manufacturing equipment. Consequently, it is my opinion that one of ordinary skill in the art would have found a suggestion to minimize the length to diameter ratio of the channel portion that terminates in the orifice of Lilley, not to lengthen it.

12. As explained on page 5 of the application, although it could be done, it is especially problematic to make the high claimed length to diameter ratios using plastic components. Since the Lilley patent explains, with specific reference to its Figs. 10 and 11, that the nozzles shown can be made from plastic materials (Lilley, 10:21-28), the common knowledge in the art would have been to minimize the length to diameter ratio of the channel, and would have found no suggestion or motivation to make a channel as claimed in claims 1, 16, or 20, or much less in claims 3, 18, 19, or 23.

13. Furthermore, the disclosure in the Lilley patent does not suggest any of the advantages of using a channel with a length to diameter ratio of above 6/1. The application explains on pages 8 and 9 and with reference to Fig. 18, that the inventors have found that using a discharge channel with the ratio of at least 6/1 allows the use of significantly lower forces applied to the mechanism that fires the jet, without resulting in a reduction in pressure when the jet is fired. The application describes that a 40 lb. energy source has been used to produce a similar injection with the claimed channel ratio as can be accomplished with a 55 lb. energy source that uses a traditional probe. In my opinion, one of ordinary skill in the art would have found that this advantage is surprising and unexpected in view of Lilley and over

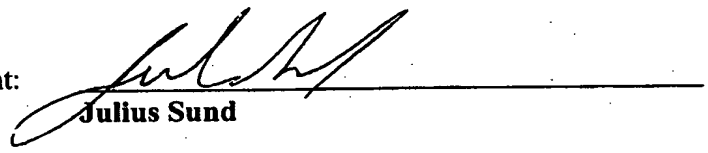
the traditional injectors known prior to the filing date of the application. This advantage provides the surprising benefits of reducing the stresses on an injector to extend its useful life and or to allow less material or less robust materials to be used in the injector.

14. Highlighting embodiments that take advantage of these surprising benefits, claim 24 recites that the steady state pressure produced is less than 4000 p.s.i., and claim 25 further recites that the energy source produces up to around 40 lbs. to inject the fluid. These parameters are lower than would have been used with lower length to average diameter discharge channels, Lilley does nothing to described or even suggest that using these parameters world work to one of ordinary skill in the art. Claim 26 further defines that the ratio is sufficiently large to jet inject the fluid with a successful injection rate into patients of at least about 98% using these parameters. While this is explained in the first paragraph on page 9 of the application, there is no suggestion, in my opinion, that a ratio of at least 6/1 would allow obtaining such a high success rate using the parameters of claims 24 and 25.

15. Consequently, it is my opinion that one of ordinary skill in the art would not find any teaching or suggestion of the claimed invention in the Lilley patent.

16. I further declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Dated this 27th day of February, 2006.

Declarant: 

Julius Sund